Maryland
2004

A Model For Increasing Availability Of Community-Based Cancer Clinical Trials In Rural Eastern Shore Maryland

Accomplishments

As of June 2004:

a) 47 patients have been enrolled in trials at the Regional Cancer Center
b) 25% of patients enrolled in SELECT, the NCI and SWOG-sponsored chemoprevention trial for prostate cancer, were rural African Americans

As of May 2004:

a) 19 cancer treatment or prevention protocols were open at the Regional Cancer Center

Since the year 2000:

a) 15 community educational programs on clinical trials are conducted annually
b) over 50 CME hours on clinical trials are conducted annually
c) over 250 health and allied health professionals attend the CME-approved clinical trials conferences and programs annually
d) weekly presentations are conducted at tumor board meeting on availability of clinical trials and the process for patient referral

Since the year 1999:

a) availability of clinical trials increased almost 8-fold from 2 in 1999 to 15 in 2003
b) the cumulative number of patients enrolled in trials increased approximately 20-fold

Introduction

Assuring diversity in clinical trials participation is a national priority. Minority, uninsured, poor, and rural-dwelling persons have a lower level of participation in clinical treatment trials compared to the general population.[1,2,3]

It has been suggested that the low participation in cancer trials by African Americans and other minorities may contribute to existing cancer survival and mortality rate disparities. These avoidable disparities in cancer research participation are a public health problem in that access to cutting edge advances in cancer prevention and therapy are not equitably available to those populations experiencing substantially higher cancer incidence, morbidity and mortality rates.[4] A variety of barriers to participation in research trials exist. These include: less effective or ineffective physician-patient interactions; lack of sufficient community infrastructure to support trials; researcher-specific obstacles, lack of adequate support for community outreach; absence of convenient transportation in rural and urban communities; lack of information on available trials; fear or distrust of academic institutions, and certain historical factors. The Coalition of National Cancer Cooperative Groups, the Cancer Research and Prevention Foundation, and the Eastern Cooperative Oncology Group have hosted the National Summit Series on Clinical Trials since 1996. The goal of this program is to increase cancer patient participation in clinical trials by 10-

15% by the year 2005. Multifaceted strategies are required to increase availability of trials at the community level and participation in such trials by the underserved patient population.

In 1993, the most recent amendment to the NIH Revitalization Act (Public Law 103-43)[5] mandates the inclusion of women and minorities in clinical research and government sponsored human subject research including clinical trials. This Act states that women and minorities must be included in all clinical research studies and must be included in Phase III clinical trials. Trials must also be designed to permit valid subgroup analyses. The act states that cost is not an allowable reason for excluding minorities and that the NIH will support outreach efforts to fulfill this mandate.

Less than 10% of United States (U.S.) cancer patients participate in cancer clinical trials.[6,7,8] Substantially fewer African American or uninsured people participate in cancer trials.[9,10] It has been established that historically most clinical trials in the U.S. take place in academic institutions, not in community settings. In 2002, the National Cancer Institute (NCI) developed a new system for clinical trials, which increased the frequency of trials in non-academic community settings.[11]

We present a program for increasing the availability of cancer trials in minority and rural communities. An equal partnership between an academic institution, the University of Maryland School of Medicine (UMSOM) and a rural community cancer center, Shore Health System's Regional Cancer Center and Eastern Shore Oncology, PC, supports this community cancer clinical trials model.

Goals and Objectives

The goals of this program are to a) increase the availability of cancer clinical trials on the Eastern Shore, an underserved rural region of Maryland, and b) increase patient enrollment in cancer trials in the community setting in Maryland.

The objectives of this program are to:

a) establish a clinical-academic partnership, which fosters increased availability of cancer trials for patients on the Eastern Shore of Maryland;
b) provide intensive health care professional continuing education on clinical trials;
c) provide intensive community awareness and educational activities on clinical trials for the general public and minority communities; and
d) provide clinical trials infrastructure support in the form of a nurse community educator and a clinical trial nurse data manager through private, federal and state funding sources.

Model

The process for increasing community-based cancer clinical trial availability and participation and the roles are discussed below. Willingness to collaborate on the part of both institutions is required and serves as the framework for implementation of this model. See Table I for details of specific activities and the timeframe for each objective.

Objective a): establish an academic-clinical clinical trial partnership

In 1999, a formal partnership was established between Eastern Shore Oncology, PC of Shore Health System's Regional Cancer Center on Maryland's rural Eastern Shore and the University of Maryland School of Medicine (UMSOM) in Baltimore, Maryland. Dr. Mary

DeShields, then medical director and medical oncologist at Shore Health System's Regional Cancer Center received an adjunct faculty appointment in the UMSOM in December 2000.

Key components of the model include: strong leadership by a local community physician, shared benefits and commitment to the partnership between a school of medicine and community cancer center; ongoing grant support by federal, private and state funds; on site nurse community educator and nurse data manager; investment in clinical trial infrastructure for data management and protocol adherence and community as well as health professional education.

The local rural oncology partner's roles are:

- Serves as the rural senior investigator for NCI sponsored trials in the non-academic community setting.
- Initiates, conducts and monitors all aspects of cancer trials in rural community. Includes assuring human subjects protections, IRB submission, and safety.
- Promotes participation in trials among local primary care and specialty physicians.
- Develops and implements local community education on cancer trials.
- Supervises nurse community educator and clinical trial nurse data manager.

The academic partner's roles are:

- Initiates partnership between rural community cancer center and school of medicine. Provides seed funding.
- Provides baseline survey research data on rural attitudes and knowledge of clinical trials. This is used to target community and physician education.
- Assists with school of medicine faculty appointment for rural oncologist.
- Foster rural underserved cancer disparities and community based research.
- Assists with research grant preparation to leverage additional funding.

The presence of an onsite clinical trials research nurse and community educator is an essential component of this model. Both positions are fully supported by grant funds.

Objectives b and c): provide intensive health care professional continuing education on clinical trials; and provide intensive community awareness and educational activities on clinical trials

The "clinical-academic partnership" promoted clinical trial participation and physician and community awareness and continuing education on clinical trials. From the year 2000 through the present, over 50 continuing medical education (CME) hours were conducted annually and included over 250 attendees. Weekly lectures were presented on available clinical trials and the process for patient referral at the tumor boards. Conferences and programs were provided to physicians and allied health professionals.

Fifteen community educational programs were conducted per year on clinical trials. Community awareness and educational programs on clinical trials were faith-based, largely churches, in neighborhood and community settings, such as health fairs, and in the community at large. Educational programs were also provided in local home settings for groups of women and men and included eighteen community and faith-based education series programs, such as "Men's Night Out", "Ladies Night Out", and a basketball tournament, among others.

Objective d): To provide clinical trials infrastructure support in the form of a nurse community educator and a clinical trial nurse data manager

Clinical trial infrastructure support for Eastern Shore Oncology, PC consists of 1) the community oncologist, 2) a nurse community educator who specializes in large community education and church education on clinical trials and 3) a clinical trials nurse data manager who specializes in extensive physician education and individual clinical trial patient education and monitoring.

Results

In a five-year period, the availability of cancer clinical trials through Shore Health System's Regional Cancer Center has increased over 700%, from two in 1999 to 15 in 2003. As of May 31, 2004, 19 cancer trial protocols, treatment and prevention, are open at the Regional Cancer Center (see Figure 1).

During this same time period, the cumulative number of patients on trials increased from only two patients in 1999 to 22 patients in 2002 and 41 patients in 2003. As of early June 2004, 47 patients have been enrolled in treatment and prevention trials at the Regional Cancer Center (see Figure 2).

Membership by the Regional Cancer Center in cancer cooperative groups and the NCI cancer trial support unit increased from zero membership in 1999 to current membership in the Eastern Cooperative Oncology Group (ECOG), Southwest Oncology Group (SWOG), and NCI Clinical Trials Support Unit (CTSU). In addition, of the Regional Cancer Center enrollees on SELECT, the NCI and SWOG-sponsored chemoprevention trial for prostate cancer, 25% of patients enrolled were rural African American.

Audit results

Clinical trials audits are an important tool for monitoring adherence to clinical trial protocols and assuring quality in all trial aspects. The audits conducted of Eastern Shore Oncology, PC to date have all been successful with no restrictions or concerns, and audit results were "passed" for CTSU, ECOG, and SWOG.

Conclusions

The feasibility and effectiveness of a model for increasing cancer trial availability in community settings for an underserved rural region of Maryland is demonstrated. Consistent with the goal of the Summit Series on Cancer Clinical Trials of the Coalition of National Cancer Cooperative Groups, this model is an important component for enhancing the quality of care and outcomes for cancer patients and contributes to discovery and advances in treatment and prevention modalities for cancer. The availability of cancer trials in a rural community setting has removed the transportation barriers experienced by rural cancer patients who have to travel long distances to academic institutions for cancer care and clinical trial participation.

Future Directions

This model will continually be refined and improved. Expansion of the number of cancer trial protocols available, both therapeutic and prevention, is a priority. As of May 2004, four additional NCI sponsored therapeutic protocols and one new prevention protocol have been opened. Increasing patient recruitment and enrollment is a continuing priority. Additional priorities include expansion of the number of community physicians referring their patients to trials at the Regional Cancer Center, increased community awareness and knowledge of the role

of clinical trials and key trial components, and greater understanding of trial design and physician knowledge of the possible risks and benefits of trial participation for their patients.

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Figure 1. The number of open cancer protocols during 1999-2004.

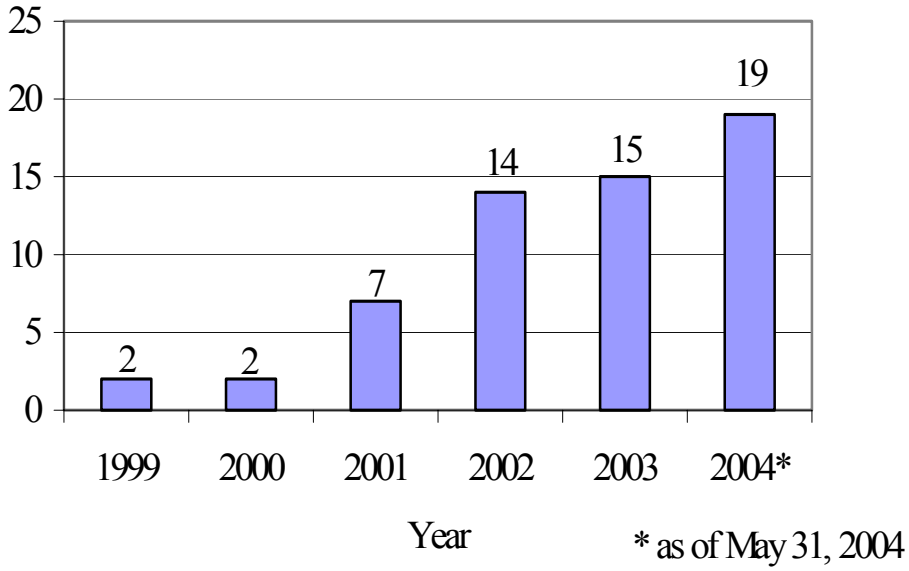

Figure 2. The cumulative number of patients on cancer protocols during 1999-2004.

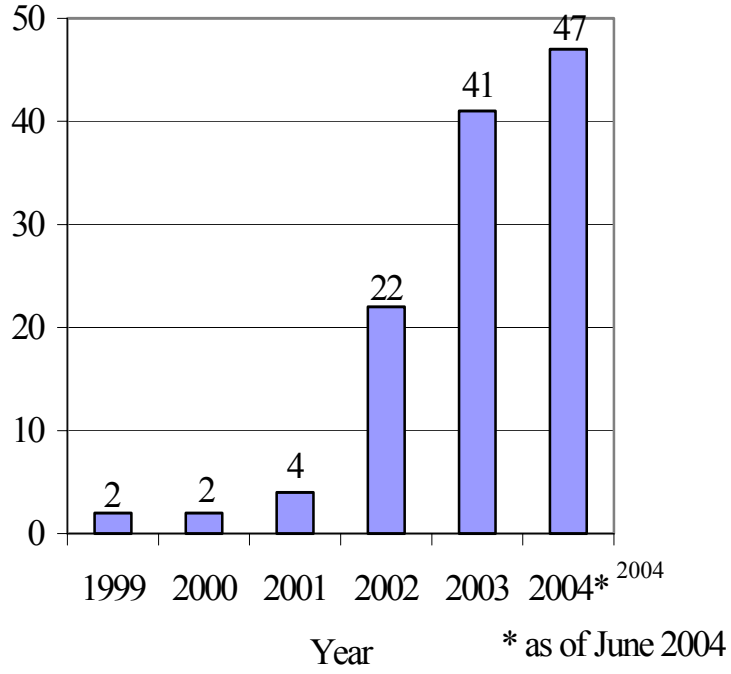

Table 1. Framework for Best Practice Model for Increasing Cancer Clinical Trials in Rural Community Settings

_____	**1999** ▪ Initiation of clinical-academic clinical trial partnership. ▪ UMSOM provides telemedicine equipment to Eastern Shore Oncology, PC. ▪ UMSOM applied for the NCI Special Population Cancer Research Network grant. **2000** ▪ The NCI Maryland Special Population Cancer Research Network (MSPN) (grant no. CA8624904: Claudia R. Baquet, MD, MPH (PI)). ▪ Eastern Shore Oncology, PC receives formal subcontract to expand education and trial availability for the Eastern Shore region. (Mary DeShields MD – subcontract PI) ▪ A nurse community educator for clinical trial education is hired. ▪ MSPN provided continuing resources for the formal "academic-clinical partnership" to promote clinical trial participation and physician and community awareness and continuing education on clinical trials. **2001** ▪ Maryland Affiliate of the Susan G. Komen Foundation awards grant to Shore Health System's Regional Cancer Center ▪ Komen grant supports on site, part-time clinical trial nurse data manger. **2002** ▪ UMSOM provides funds from UMSHN grant (Maryland Tobacco Settlement) to support trial infrastructure and expansion of community and physician education on clinical trials. ▪ On site clinical trials nurse data manager is converted to full-time position ▪ Telemedicine equipment, supported by the UMSHN, is upgraded to newer equipment, which allows review of radiology studies in remote sites. ▪ Higher bandwidth resulting from these upgrades allows improved images for videoconference sessions involving churches on the Eastern Shore and in Baltimore City.
_____	**2000-present** ▪ MSPN provided continuing resources for the formal "academic-clinical partnership" to promote clinical trial participation and physician, nurse and allied health professionals awareness and continuing education on clinical trials. ▪ Over 50 continuing medical education (CME) hours were conducted and included over 250 attendees. Physicians and allied health professionals gained these CE credits through weekly presentation of available trials and the process for referral at the tumor board.
_____	**2001-present** ▪ Minimum 15 formal community educational programs per year on clinical trials ▪ In home, church, general community educational programs presented on routine basis. ▪ Men's night out; Ladies night out; annual basketball tournament feature lectures on clinical trials
Objective d) **To provide clinical trials infrastructure support in the form of a nurse community educator and a clinical trial nurse data.**	**2001-present** ▪ Received support from the Maryland Affiliate of the Susan G. Komen Foundation for onsite, part-time clinical trial nurse data manager. **2002-present** ▪ UMSOM provided state resources through a grant from the Maryland Cigarette Restitution Fund (grant no. CH605CRF) to support increased community clinical trials infrastructure on the Eastern Shore. This grant provides support for a clinical nurse educator at Eastern Shore Oncology, PC. ▪ Support from this UMSOM grant is also provided for research nurse training on updates on regulatory and patient safety issues for clinical trials. ▪ UMSHN gives funds to Shore Health System to increase clinical trial nurse data manager to a full time position.

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Funding Sources: This partnership was supported by several funding sources including:

- In 1999, a "Dean's grant" to purchase telemedicine equipment for videoconferencing for tumor boards, clinical trial meetings and patient consultations.
- From 2000-present, UMSOM provided funding to Eastern Shore Oncology through the "Maryland Special Populations Cancer Research Network" (grant no. NCI 5CA86249) cooperative agreement. Dr. Mary DeShields serves as Principal Investigator for this rural oncology subcontract.
- In 2001, the Maryland Affiliate of the Susan G. Komen Foundation awarded a grant to Dr. DeShields to support an onsite, part-time clinical trial nurse data manager at the Regional Cancer Center.
- From 2002-present, UMSOM provided supplemental funding to Eastern Shore Oncology, Inc. from its Maryland Cigarette Restitution grant, the "University of Maryland Statewide Health Network".